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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/205,251	12/04/1998	IRVING K. ARENBERG	INTRUS-4	8010

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EXAMINER	
STIGELL, THEODORE J	
ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
06/02/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/205,251	ARENBERG ET AL.	
	Examiner	Art Unit	
	THEODORE J. STIGELL	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26,28,29,54-60,66-68,70-78 and 80-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26,28,29,54-60,66-68,70-78 and 80-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 26, 28-29, 66-68, 70-71, 75-78, and 80-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manning et al. (WO 97/38698)

Manning et al. disclose the invention substantially as claimed. Manning et al. disclose a drug delivery unit comprised of a biocompatible, biodegradable polymer support and at least one pharmacologically active agent that is placed such that it substantially contacts the round membrane of the middle ear. See page 4, lines 11-14, page 5, lines 9, page 6, lines 24-30. This would encompass the being in direct contact or against and "at least partially in said round window niche". With respect to the

location of the drug delivery unit, it is disclosed on page 1, lines 19-21 that "access to the inner ear tissue regions is typically through a variety of structures including the round window membrane "... etc. That would narrow it to the location between the tympanic membrane and the round window that is the location of the round window niche since it is also disclosed that the drug delivery unit is in contact with the round membrane of the middle ear. Manning et al. teach that the device provides extended release. See page 4, lines 5-20 and abstract. On page 7, lines 7-12. Manning disclose the drug concentration can be varied over broad limits and is chosen depending upon solubility, pharmacological activity, desirable effect of the end product, patient size and weight all factors know to those skilled in the art. As for the language of the "the biocompatible polymer" it is well known in the art that that would be a synthetic as opposed to a "biopolymer" which is naturally occurring. With respect to the quantity of agent to be 10-40 wt %, Manning teaches the unit to be 0.05 to 4% wt and higher. See page 3, lines 8-15, page 4, lines 1-30, page 5, lines 8-23, page 7, lines 7-15, page 8, lines 8-15 and see claims 1-22. However, Manning does not disclose the specific volume of the drug delivery unit being 0.1 mm^3 and 250 mm^3 or any of the other limitations of the length and diameter of the unit. Manning teaches the drug delivery unit to be delivered into the middle and inner ear. It would have been obvious to one of ordinary skill in the art that the device of Manning would encompass such a broadly claimed range of the volume although he does not disclose the volume specifics of his device. Thus, it would have been obvious to one of ordinary skill in the art to modify the volume size as claimed as a mere design choice lacking any criticality of size as being

merely preferable for the intended target (ear) area depending on the size of the ear of the patient where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. With respect to the agent in nanogram to microgram quantities or the timing of the release of the agent, Manning teaches the dose to be preferably between 5-360 mg. However, Manning also teaches that those skilled in the art can determine optimal doses and dosage schedules. It would have obvious to one of ordinary skill in the art at the time the invention was made to modify the dosage or dosage schedules to one which is desired for the patient taking into consideration the parameters of the patient such as size, weight, severity of the condition of the disease in order to deliver therapeutically effective levels of drug to the patient that is prompt, prolonged, effective and safe.

Claims 54-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manning et al. (WO 97/38698).

Manning teaches the invention as substantially claimed. See above. Manning specifically teaches a biocompatible polymer. However, Manning does not teach the material to be polyanhydride material, polyorthoester material, hydroxypropylmethyl cellulose, hydroxyethyl cellulose, hydrophilic microsphere, bioadhesive material, or a multiphased material. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the polymer material as a mere design choice to which the polymer is more available for use, cheaper, etc. for those skilled in the art.

The material is not critical to the invention unless the material is some newly discovered material.

Claims 72-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manning et al. (WO 97/38698) in view of Peterson (U.S. Patent No.4,472,394).

Manning et al. teaches the invention as substantially claimed. See above. However, Manning can be further supported by varying the time release of the agent by the teachings of Peterson. Peterson teaches implanting a pellet/ruminant beneath the ear for extended controlled release of the active ingredient over a period of 60 days to 210 days. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the period of release of the drug of Manning et al. with a period of greater than a month as taught by Peterson in order to provide uniform extended release depending on the parameters (such as weight of patient, type of drug, solubility of drug, etc.) required for a dosing regiment. Further lacking any criticality or unexpected results, it would have been obvious to modify the time period since slow release and controlled release is well known in the medical arts when treating the patients with respect to severity of the disease and patient's medical history.

Response to Arguments

Applicant's arguments filed 1/30/2009 have been fully considered but they are not persuasive. In response to the applicant's argument that Manning does not disclose the polymer configurations recited by the applicant, the examiner respectfully disagrees. The examiner contends that the polymer configurations of Manning are broad enough to

read on the broad configurations recited by the applicant. Manning discloses using a carrier material in the form of a gel composition system that is "capable of maintaining its position in order to provide a surface that substantially contacts the round membrane of the middle ear" (see page 4, lines 5-14). Clearly, the gel has enough support to maintain a shape for a period of time. The examiner notes that the applicant has claimed a broad range of shapes that the gel of Manning could certainly embody.

In response to the applicant's argument that Manning does not disclose insertion of a drug unit directly into the subject niche, the examiner respectfully disagrees. The examiner references the same sections of Manning. Manning clearly discloses that the composition "substantially contacts the round membrane of the middle ear" and provides "extended release of active agent to the inner ear". Therefore, the examiner is confused by the applicant's assertion that the therapeutic of Manning "will not even contact the round window membrane (see page 7 of applicant's response). For these reasons, the applicant's arguments are not found to be persuasive.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THEODORE J. STIGELL whose telephone number is (571)272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Theodore J Stigell/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763